UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

PFIZER INC., PFIZER LTD.,

and

PFIZER IRELAND PHARMACEUTICALS,

Plaintiffs,

v. **Civil No. 2:10cv128**

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

MEMORANDUM ORDER

This matter comes before the court on motion of defendant and counterclaimant Teva Pharmaceuticals USA ("Teva") to amend its answer and counterclaim. For the reasons which follow, this court **GRANTS** the motion but **ORDERS** Teva to file a revised amended answer and counterclaim in accordance with the court's decision set forth herein.

I.

Pfizer Inc., Pfizer Ltd., and Pfizer Ireland Pharmaceuticals (collectively "Pfizer") filed suit in this court on March 24, 2010, seeking injunctive and declaratory relief for anticipated patent infringement by Teva.[1] In essence, Pfizer alleges an imminent threat

[1] Pfizer brought suit against two defendants: Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. The complaint against Teva Pharmaceutical Industries was dismissed without

that Teva will infringe Pfizer's patent entitled "Pyrazolopyrimidinones for the Treatment of Impotence" ("the '012 patent"). The '012 patent claims a number of chemical compounds for the treatment of erectile dysfunction ("ED"), one of which is the active ingredient in the drug Viagra, sildenafil. Pfizer alleges that Teva will infringe the patent by manufacturing a generic version of Viagra. On April 29, 2010, Teva answered the complaint and filed a counterclaim against Pfizer seeking a declaration that the claims of the '012 patent are invalid in their entirety, such that Teva's planned drug will not infringe any patentable claim. Pfizer answered Teva's counterclaim on May 20, 2010.

Subsequently, on November 12, 2010, Teva moved to amend its answer and counterclaim. In particular, Teva asks the court to allow amendment of its answer and counterclaim to add the allegation, both as an affirmative defense and as part of its declaratory judgment action, that the '012 patent is invalid because Pfizer engaged in inequitable conduct during its prosecution and reexamination of the '012 patent. Pfizer responded in opposition to Teva's motion on November 29, 2010. Teva replied on December 6, 2010. On December 8, 2010, Pfizer filed a supplemental notice with the court, alerting

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prejudice upon agreement of the parties on May 4, 2010. See ECF # 26.

the court to the execution of a covenant not to sue Teva on the animal claims of the patent, Claims 1-23, which claims are the subject of Teva's inequitable conduct assertion.[2] The court heard argument on the Motion to Amend on December 13, 2010, and it is now ripe for decision.

II.

Federal Rule of Civil Procedure 15(a)(1)(A) provides, in pertinent part, that "[a] party may amend its pleading once as a matter of course . . . before being served with a responsive pleading." If a party seeks to amend its pleading in any other situation, it may only do so "with the opposing party's written consent or the court's leave," and the "court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). The Fourth Circuit[3] has held that "leave to amend a pleading should be denied only when the amendment would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or the

[2] A copy of the covenant not to sue was attached to the notice filed with the court. See ECF # 64.

[3] The standard for whether a motion to amend should be granted in a patent case is a matter of the relevant circuit's law in the district where the case is filed and/or pending, not that of the Federal Circuit. Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1318 (Fed. Cir. 2009).

amendment would have been futile." Laber v. Harvey, 438 F.3d 404, 426 (4th Cir. 2006) (emphasis added) (citing Johnson v. Oroweat Foods Co., 785 F.2d 503, 509 (4th Cir. 1986) and Foman v. Davis, 371 U.S. 178, 182 (1962)). That rule reflects the federal policy of "resolving cases on their merits instead of disposing of them on technicalities." Sciolino v. City of Newport News, 480 F.3d 642, 651 (4th Cir. 2007).

A party seeking to amend its pleadings must meet the pleading requirements for the particular cause of action it seeks to bring to avoid denial on the basis of futility. The Federal Circuit has held that a party asserting a claim of inequitable conduct must plead it with the specificity required by Federal Rule of Civil Procedure 9(b). Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1328 (Fed. Cir. 2009); see Fed. R. Civ. P. 9(b).[4] Thus a party must "identify the specific who, what, when, where, and how of the material misrepresentation or omission committed" before the Patent Trademark Office ("PTO") for a claim of inequitable conduct to satisfy Rule 9(b). Exergen, 575 F.3d at 1328. In other words, the pleadings "must include sufficient allegations of underlying facts from which

[4] In patent cases before the district court, Federal Circuit law determines whether inequitable conduct has been pleaded with the particularity required. Exergen, 575 F.3d at 1328.

a court may reasonable infer that a specific individual (1) knew of the withheld material information or the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." Id. at 1328-29. If the party seeking amendment to add a claim of inequitable conduct fails to meet the requirements of Rule 9(b), the amendment must be denied as futile. Id. at 1331; United States ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 376 (4th Cir. 2008).

III.

Teva has moved to amend its answer and counterclaim to add the claim for declaratory judgment, and as an affirmative defense, that inequitable conduct by Pfizer invalidates the '012 patent in its entirety. The inequitable conduct Teva alleges, in essence, is that Pfizer actively prosecuted the '012 patent to include claims that the treatment would benefit a "male animal" with ED.[5] This, Teva argues, was inequitable conduct because Pfizer knew that the animal claims were overbroad and unpatentable; Pfizer withheld information from the PTO that demonstrated the unpatentability of the claims;

[5] Claims 1-23 of the '012 patent mention that the chemical compound claimed therein may be used to treat ED in a male animal.

and Pfizer continued to espouse the animal claims in the reexamination of the patent. Teva argues because Pfizer expressly disclaimed the animal claims in the prosecution of the Canadian patent for the same chemical compounds as the '012 patent soon after the '012 patent issued in the United States, it shows Pfizer was aware that such claims were unpatentable.[6] Teva alleges that counsel representing Pfizer in the United States patent prosecution were aware of this admission of overbreadth but did not raise it during the reexamination.

Pfizer opposes Teva's motion on the grounds that Teva has failed to meet the pleading requirements of Rule 9(b), such that amendment would be futile, and that Teva's inferences concerning Pfizer's intent to deceive are unreasonable.[7] Specifically, Pfizer argues that Teva's blanket statements, namely that Pfizer's in-house and external counsel involved in the patent prosecution along with the patent's chief inventor acted inequitably, are insufficient to fulfill Exergen's requirement that the "who" and "what" of the

[6] Pfizer disclaimed the animal claims in the Canadian patent when that patent was challenged by Bayer AG and Bayer, Inc. for being overbroad.

[7] Pfizer does not allege that the amendment would be either prejudicial or is done in bad faith, and thus those elements need not be addressed by the court.

inequitable conduct be named with specificity. See 575 F.3d at 1328-29. Furthermore, Pfizer argues that there in insufficient evidence that its conduct was inequitable because the disclaimer in Canada related to a patent worded in a materially different way than the '012 patent,[8] and because once the reexamination of the patent began in the United States, Pfizer disclosed the disclaimer. Finally, Pfizer has provided a covenant not to sue on the animal claims in the patent which demonstrates, it argues, that Pfizer did not and would not engage in inequitable conduct to preserve claims that have so little value as to be willingly disclaimed.[9]

Though it is a close question, this court is of the opinion that Teva has met the requirements of Rule 9(b). Teva has identified the particular individuals working for Pfizer during the patent prosecution and reexamination process who allegedly engaged in the

[8] The Canadian patent referred to treating animals with erectile dysfunction, while the American patent refers to treating animals in need of treatment for erectile dysfunction.

[9] Importantly, both parties agree that Pfizer's disclaiming of the animal claims in the patent does not prevent Teva from pursuing a claim of inequitable conduct because such conduct, if proven, would invalidate the entire patent, not just the animal claims at issue. See Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 877 (Fed. Cir. 1988); Amgen, Inc., v. Ariad Pharmaceuticals, Inc., 577 F. Supp. 2d 702, 713-14 (D. Del. 2008).

inequitable conduct,[10] and Teva has identified the substance of the materially false or omitted information.[11] The point where Teva's allegations are the most strained is the requirement that it demonstrate that Pfizer had the "specific intent to deceive the PTO." Exergen, 575 F.3d at 1328-29. Teva alleges that Pfizer either omitted information about the Canadian disclaimer, or "buried" the disclosure, with the intent to occupy the field and claim a monopoly on the use of sildenafil. At this stage, however, as this is neither a motion to dismiss nor a motion for summary judgment from Pfizer, Teva has sufficiently met the requirements of Rule 9(b) as interpreted by Exergen by alleging the material information that was withheld, who did the withholding, and that the intent thereby to deceive the PTO. The court thus **GRANTS** Teva's motion.

IV.

The court does not, however, order Teva's proposed amended answer and counterclaim to be filed. Instead, the court **ORDERS** that

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[10] The proposed amended counterclaim names Dr. Peter Ellis, the chief inventor of the '012 patent, as well as Gregg C. Benson and James T. Jones, Pfizer's internal counsel, and Gerald M. O'Rourke, Pfizer's external counsel.

[11] The substance of the materially false information, or withheld material information, is composed of Teva's allegations concerning the animal claims as previously set forth. See supra at 5-6.

Teva file a revised amended answer and counterclaim which reflects the current controversy before the court and the court's rulings in this Memorandum Order.

While Pfizer's covenant not to sue on the animal claims does not prevent Teva from pursuing a claim on inequitable conduct,[12] it does deprive Teva's suit for declaratory judgment of subject matter jurisdiction as to those claims. Amgen, Inc., v. Ariad Pharmaceuticals, Inc., 577 F. Supp. 2d 702, 713 (D. Del. 2008). Counsel for Teva at the hearing acknowledged this, stating that the covenant not to sue "does moot our declaratory judgment with respect to seeking invalidity of the animal claims." Markman Hr'g Tr. at 138 (Dec. 13, 2010). Thus, the parties agree that the only claims remaining before the court for decision upon declaratory judgment are Claims 25 and 26. Id. ("The claims remaining before the court would be, as you know, Claims 25 and 26."); Id. at 147 ("[W]e have been endeavoring over time to get a covenant not to sue to them which, one, would narrow the case, putting aside the inequitable conduct issue completely, just narrow the case to Claims 25 and 26 so we wouldn't be dealing with claims that we didn't assert in this case.").

[12] See supra note 9.

Teva's proposed amended answer and counterclaim as submitted with its Motion to Amend its Answer and Counterclaim does not reflect this lack of jurisdiction and instead seeks declaratory judgment as to all claims of the '012 patent. Therefore, the court **DIRECTS** that Teva file an amended answer and counterclaim within ten (10) days of this Memorandum Order which limits its counterclaim to Claims 25 and 26 of the patent.[13] Pfizer shall have seven (7) days from the date of the filing of the amended answer and counterclaim in which to respond.

V.

Accordingly, the court **GRANTS** Teva's Motion to Amend its Answer and Counterclaim. However, the court **DIRECTS** that Teva file a revised amended answer and counterclaim with the court which reflects only Claims 25 and 26 at issue for declaratory judgment.

The court **DIRECTS** the Clerk to send a copy of this Memorandum Order to all counsel in this case.

IT IS SO ORDERED.

/s/ RBS
Rebecca Beach Smith
United States District Judge

January 18, 2011

[13] Teva may of course refer to the animal claims, Claims 1-23, in its allegations of inequitable conduct because such allegations, if proven, would invalidate the patent in its entirety.